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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,100	08/21/2003	**Zahir Saidi**	P24,800-A USA	8648

7590 04/15/2009

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EXAMINER	
SOROUSH, LAYLA	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
04/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/019,100	SAIDI ET AL.	
	Examiner	Art Unit	
	LAYLA SOROUSH	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-10 and 13-27* is/are pending in the application.

4a) Of the above claim(s) *5,7-9 and 18-21* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,10,13-17 and 22-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The response filed January 27, 2009 presents remarks and arguments submitted to the office action mailed October 28, 2008 is acknowledged.

Applicant's arguments over the 35 U.S.C. 103(a) rejection of claims 1, 6, 10, 13-17 and 22-27 over Sonne (US Pat No. 6,193,985– previously presented) is not persuasive. Therefore, the rejection of record is maintained.

Applicant makes no arguments regarding the ODP rejection made over U.S. Patent No. 6241969. Therefore, the rejection of record is maintained.

The rejections are restated below for Applicant's convenience.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6, 10, 13-17 and 22-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sonne (US Pat No. 6,193,985– previously presented).

The invention reads on a composition consisting of: (a) from 5 ug/mL to about 5 mg/mL of a corticosteroid in dissolved form; (b) from about 0.1 to 20 percent by weight of a pharmaceutically acceptable, high-HLB surfactant component, wherein the HLB of the surfactants present in the high HLB surfactant component comprises at least 50% by weight of an ethoxylated derivative of vitamin E, wherein said ethoxylated derivative

of vitamin E is the sole vitamin E component of the composition; and (c) at least about 70 weight percent aqueous phase.

Sonne discloses an oil in water emulsion of budesonide as nose drop or nasal spray, comprising in the oily phase 0.025 grams of budesonide, 5 grams of vitamin e TPGS and 12.5 grams alpha-tocopherol – (viscous oil (surfactant)) (see col 3 line 18, col 11 Example 15). The limitation of the composition having at least about 70 weight percent of aqueous phase is met by the teachings of the water phase in the prior art (col 11 Example 15). Additionally, Sonne et al. teaches "Generally speaking compositions of the invention may contain from 1 to 99.99% (w/w), preferably 20 to 99.99%, most preferably 40 to 99.99% (w/w) of the tocopherol or tocopherol derivative solvent. The emulsion used in compositions of the invention may contain 1 to 95% (w/w) of the tocopherol or derivative thereof, preferably 20 to 95% (w/w), most preferably 35 to 80% (w/w) (Col 5 lines 55-61)." Sonne teaches "the formulations according to the invention may be optimized with respect to bioadhesion, sprayability and viscosity, as desired. Thus for example, the following co-solvents may be added: Vegetable oils such as sesame- or olive- or fractionated coconut oil, alcohols such as ethanol, propylene glycol, glycerol, polyethylene glycol or benzyl alcohol; or triacetin, (col 6 lines 47-59)" meeting the limitation of claims 15 and 17. Further, Sonne teaches "the tocopherol derivative emulsifier of the invention may be used alone or in conjunction with other known emulsifiers eg. phospholipids, polysorbates, sorbitan esters of fatty acids, cetearyl glucoside or poloxamers. It has furthermore surprisingly been shown that various other

solvents may be used in the emulsion system described above, without compromising the stability of the emulsion (col 4 lines 50-56)."

Sonne fails to exemplify a composition "wherein said ethoxylated derivative of vitamin E is the sole vitamin E component of the composition," or comprising a high-HLB surfactant component of at least 50%, 75%, 90% by weight tocopheryl polyethylene glycol 1000 succinate. Further, Sonne does not exemplify a composition containing from about 0.1 to about 20 percent by weight of a pharmaceutically acceptable cosolvent comprising propylene glycol, polyethylene glycol having a molecular weight between about 200 and 4000, glycerol, ethoxydiglycol, glycofurol, and ethanol, or a combination thereof, 0.1 to about 3 percent by weight of phospholipids, nor 0.1 to about 3 percent by weight of an oil.

However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the composition by substituting the alpha-tocopherol of Example 15 with a vitamin e-TPGS and incorporating additional ingredients such as oils or alcohols inclusive of ethanol, propylene glycol, glycerol, polyethylene glycol or benzyl alcohol; or triacetin, or emulsifiers eg. phospholipids, polysorbates, sorbitan esters of fatty acids, cetearyl glucoside or poloxamers. The motivation to make such an incorporation is because Sonne teaches (1) it has been surprisingly found "that tocopherol derivatives, particularly certain esters, may themselves form efficient, non-irritating emulsifiers to enable stable emulsions to be formed, even where high lipid levels are involved eg. about 50-70%. Particular mention may be made in this regard of Vitamin E TPGS which is a water soluble derivative of Vitamin E and consists of .alpha.-

tocopherol, which is esterified with succinic acid, the other acidic group of the latter being esterified with polyethylene glycol 1000. Vitamin E TPGS is an almost odourless waxy amphiphilic substance with a molecular weight about 1513 (col 4, lines 27-35);" (2) the formulations according to the invention may be optimized with respect to bioadhesion, sprayability and viscosity, as desired. Thus for example, the following co-solvents may be added: Vegetable oils such as sesame- or olive- or fractionated coconut oil, alcohols such as ethanol, propylene glycol, glycerol, polyethylene glycol or benzyl alcohol; or triacetin and (3) the tocopherol derivative emulsifier of the invention may be used alone or in conjunction with other known emulsifiers eg. phospholipids, polysorbates, sorbitan esters of fatty acids, cetearyl glucoside or poloxamers. It has furthermore surprisingly been shown that various other solvents may be used in the emulsion system described above, without compromising the stability of the emulsion. Hence, the skilled artisan would have had reasonable expectation of successfully producing a composition that is non-irritating with optimized bioadhesion, sprayability, viscosity, without compromising the stability of the emulsion.

Further, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the dose range of the Sonne composition by routine experimentation (see 2144.05 11). The motivation to optimize the dose range of the Sonne 's final formulation is because one would have had a reasonable expectation of success in achieving the safest clinical outcome.

The composition "suitable for administering a therapeutic dose of a corticosteroid to the respiratory tract" is an intended use and does not receive patentable weight in a composition claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 6, 10, 12-17, and 22-27 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 6241969 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the invention herein is directed to a composition suitable for administering a therapeutic dose of a corticosteroid to the respiratory tract, consisting essentially of: (a)from about 5 ug/ml to about 5 mg/ml of a

corticosteroid in dissolved form, (b)from about 0.1 to about 20 percent by weight of a pharmaceutically acceptable, high-HLB surfactant component, wherein the HLB of the surfactants is greater than about 10, and (c) at least about 70 weight percent aqueous phase whereas, the Patent is directed to an aerosolized composition for administering a therapeutic dose of a corticosteroid to respiratory tract, consisting essentially of: (a) from 5 ug/mL to about 5 mg/mL of a dissolved corticosteroid; (b) from about 0.1 to about 20 percent by weight of a pharmaceutically acceptable, high-HLB surfactant component containing one or more surfactants having an HLB of greater than 10, wherein The high-HLB surfactant component comprises at least 50% by weight of an ethoxylated derivative of vitamin E; and (c) at least about 70 weight percent aqueous phase.

Response to Arguments

Applicant's arguments filed January 27, 2009 have been fully considered but are not persuasive.

Applicant argues the alpha-tocopherol is the most crucial element of the Sonne reference and that Sonne does not provide any motivation to remove alpha-tocopherol from his composition.

Examiner states that Sonne clearly discloses “the use of a tocopherol or a derivative thereof as a solvent and/or emulsifier for substantially insoluble and sparingly soluble biologically active agents, especially in the manufacture of pharmaceutical compositions (see abstract).” It is respectfully stated that the 35 U.S.C. 103(a) rejection above is not a anticipatory rejection. Though, the reference does not exemplify the sole use of vitamin E TPGS in a composition, one of ordinary skill in the art would have been readily

motivated to utilize a tocopherol derivative in order to produce an efficient, non-irritating, and stable emulsion because Sonne teaches the use of a tocopherol or a derivative thereof.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

The arguments are not persuasive and the rejection is made **FINAL**.

Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617